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TITLE: Legacy Clinical Data from the Epo TBI Trial

PRINCIPAL INVESTIGATOR: Claudia S. Robertson, MD

CONTRACTING ORGANIZATION: Baylor College of Medicine
Houston, Texas 77030

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14. ABSTRACT The goal of this proposal is to submit legacy data from 200 patients to FITBIR. We have completed preparation of the database by obtaining GUIDs for all patients and removing all protected health information. We have identified the variables that can be mapped to the existing Common Data Elements and which variables will have to be submitted as new variables. All of the new variables have been constructed and are approved or awaiting approval by FITBIR. Most of the form templates are complete or are awaiting approval by FITBIR. Once all of the form templates have been approved by FITBIR, we should be able to validate the forms and then download our data.					
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1. INTRODUCTION:

We have valuable clinical research data from 200 patients enrolled in our phase II clinical trial entitled “Effects of Erythropoietin (Epo) on Cerebral Vascular Dysfunction and Anemia in Traumatic Brain Injury (TBI)” which we will share with other investigators through the Federal Interagency Traumatic Brain Injury (FITBIR) Informatics System. This trial was funded by National Institute of Neurological Disorders and Stroke (NINDS) grant #P01-NS38660. The study began in May 2006, and completed enrollment in August 2012 and follow-up in February 2013. The data was collected prior to the completion of the Common Data Elements (CDEs) for TBI, and therefore requires work to convert the data to the format required by FITBIR.

2. KEYWORDS:

Traumatic brain injury
Erythropoietin
Anemia
Transfusion threshold

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Objectives/Hypothesis:

The goal of this proposal is to submit legacy data from 200 patients to FITBIR.

The specific aim of the project is:

Specific aim 1. To format clinical/research data from 200 patients enrolled in our Epo clinical trial so that the data can be submitted to FITBIR for sharing with other investigators.

Major Task 1: Obtain pseudo GUIDs and de-identify data

Subtask 1: Obtain pseudo GUIDs for all patients

Subtask 2: Remove all PHI, and other information that would be considered identifiers

Subtask 3: Remove other information such as dates that would be considered identifiers

Milestone(s) Achieved: dataset is de-identified (Month 1)

Major Task 2: Map variables which are compatible to the existing TBI CDEs

Subtask 1: Verify which of the variables included in our database will be important to submit.

Subtask 2: Determine which of the variables that are to be submitted have compatible definitions in the TBI CDEs and map the values in our database to the permissible values in the CDEs.

Subtask 3: Define recoding/data transformation necessary for CDE format.

Milestone(s) Achieved: Variables compatible with CDE definitions are recoded/transformed (Month 4)

Major Task 3: Create new data elements

Subtask 1: For variables that do not have compatible definitions in the TBI CDEs, create new variables (UDEs).

Subtask 2: Submit UDE metadata to FITBIR for approval

Subtask 3: Create new data tables containing the reconfigured data in FITBIR CDE/UDE format.

Subtask 4: Build, review, approve all FITBIR data forms

Milestone(s) Achieved: New data tables in FITBIR CDE/UDE format created (Month 15)

Major Task 4: Submit data to FITBIR

Subtask 1: Build, review, approve all FITBIR data forms

Subtask 2: Test FITBIR validation tool with sample data

Subtask 3: Upload data to FITBIR

Subtask 4: Enter queries to review the data, correct any problems identified in data

Milestone(s) Achieved: data successfully uploaded to FITBIR (Month 17)

What was accomplished under these goals?

Major Task 1 was completed during the first quarter – pseudoGUIDs have been received from Alice Garcia, and the database has been de-identified

Major Task 2 has been completed.

Major Tasks 3/4: Personnel changes at FITBIR temporarily slowed getting approval of variables and of form templates. Despite this, considerable progress has been made during the past quarter, and we are close to being able to download the trial data. Details of the forms that have been completed are listed in the table below. All of the UDEs have been constructed and are approved or awaiting approval by FITBIR. Most of the form templates are complete or are awaiting approval from FITBIR. Once all of the form templates have been approved by FITBIR, we should be able to validate the forms and then download our data.

Form Structure	Subtask 3-1	Subtask 3-2	Subtask 3-3	Subtask 3-4	Subtask 4-1	Subtask 4-2	Subtask 4-3	Subtask 4-4
Adverse Events	completed	completed	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Baseline Risk Assessment	completed	awaiting confirmation	in progress	awaiting confirmation	awaiting confirmation	not started	not started	not started
Consent	completed	awaiting confirmation	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Death report	completed	completed	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Discharge status	completed	completed	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
DemogrFITBIR Appdx	completed	completed	completed	completed	completed	completed	not started	not started
ER	completed	awaiting confirmation	in progress	awaiting confirmation	awaiting confirmation	not started	not started	not started
GOS	completed	completed	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Imaging	completed	submitted to FITBIR	in progress	in progress	in progress	not started	not started	not started
Meds	completed	completed	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Labs	completed	awaiting confirmation	in progress	in progress	in progress	not started	not started	not started
Prehospital	completed	awaiting confirmation	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Significant history	completed	completed	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Study discontinuation	completed	awaiting confirmation	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Study drug dosing	completed	completed	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Surgery	completed	awaiting confirmation	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Vital signs	completed	awaiting confirmation	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started
Weight	completed	completed	completed	awaiting confirmation	awaiting confirmation	not started	not started	not started

not started	have not initiated task (pending previous steps)
in progress	initiated the task and in progress
submitted to FITBIR	submitted the task to FITBIR
awaiting confirmation	submitted the task to FITBIR, and waiting for confirmation by FITBIR about some pending issues
completed	completed the task

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

Nothing to report

What do you plan to do during the next reporting period?

We plan to continue as outlined in the SOW - to continue to develop any new UDEs that are necessary, then develop the case report forms and submit the data. Transformed data in those form structures will be validated when the form structures are approved.

4. IMPACT:

What was the impact on the development of the principal disciplines of the project

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Nothing to report

6. PRODUCTS:

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

What individuals have worked on the project?

Personnel: Claudia Robertson, MD

Project role: PI

Nearest person month worked: 0.6

Contribution to project: supervised all aspects of the work, provided clinical expertise

Personnel: Jose-Miguel Yamal, PhD

Project role: CoPI

Nearest person month worked: 2.4

Contribution to project: developed FITBIR forms, converted database elements to CDE variables

Personnel: Michael Gonzalez

Project role: Programmer analyst

Nearest person month worked: 4.8

Contribution to project: provided database management/programming support

Personnel: Hyunsoo Hwang

Project role: Graduate research assistant

Nearest person month worked: 6

Contribution to project: assisted Dr. Yamal with developing the FITBIR forms and converting database elements to CDE variables

Has there been a change in the active other support of the PD/PI or senior/key personnel since the last reporting period?

For Dr. Robertson, two grants that were previous listed as PENDING (2R44NS076167-02A1 and the TBI Endpoints Development (TED) are now active. No changes for Dr. Yamal.

What other organizations were involved as partners?

Organization name: University of Texas Health Sciences Center at Houston

Location of organization: Houston, Texas

Partner's contribution to the project: collaboration

8. SPECIAL REPORTING REQUIREMENTS:

None

9. APPENDICES:

None